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10/621,972

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EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/621,972 | Applicant(s) TSUGITA, ROSS S. | |
| | Examiner Eric Blatt | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-52 is/are pending in the application.
- 4a) Of the above claim(s) 47-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 47-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on Oct. 10, 2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (WO 99/22673) in view of Littleford et al. (5,054,500).

Gray discloses guidewire 30, filter 50 and stent (page 6, lines 15-17). Gray fails to disclose a first catheter shaft (claim 32) or outer catheter shaft (claim 41) with a balloon coupled thereto. However, Littleford et al. teach that a guiding catheter 20 with a balloon 24 should be used with a treatment catheter 30 in order to obtain the advantage of centering the treatment catheter 30 within the vasculature while the balloon 24 holds the guiding catheter in place (col. 3, lines 10-28). It would have been obvious to use a guiding catheter with a balloon with the Gray treatment catheter so that it too would have this advantage. The guiding catheter is the claimed "first catheter

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shaft" (claim 32) or "outer catheter shaft" (claim 41). The Littleford et al. balloon 24 (figures 2-8) is configured to stop fluid from outside the catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft as now claimed. As to claims 33 and 38, Gray fails to disclose that the stent is self expanding and is retained in a collapsed configuration by a retaining sleeve. However, it is old and well known in this art to make stents self-expanding in order to obtain the advantage of enabling them to automatically expand when released by the retaining sleeve. It would have been obvious to make the Gray stent self expanding so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03).

Upon providing a guiding catheter as taught by Littleford, the catheter shaft of Gray (the claimed "second catheter shaft") is slidably disposed within said guiding catheter. Since the stent is provided on the second catheter shaft proximal the filter 50, the stent is configured to be slidably positioned between the distal end of first catheter shaft and the filter, and may be deployed from said position.

Regarding claim 35, Gray discloses that the second catheter shaft comprises a lesion treatment device such as a balloon or a stent (page 6, lines 15-17). The Examiner takes official notice that it was old and well known to provide a stent over a balloon in order to aid in expanding the stent in a bodily lumen. Although Gray does not explicitly disclose providing the stent disposed about the balloon, it would have been obvious to one of ordinary skill at the time of the invention to provide the stent such that it is disposed about the balloon in order to aid in expanding the stent in a bodily lumen.

Double Patenting

Claims 32-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,168,579. Although the conflicting claims are not identical, they are not patentably distinct from each other because the slight difference in the wording of the claims involves only an obvious difference.

Response to Arguments

Applicant's arguments filed March 24, 2008 have been fully considered but they are not persuasive.

Applicant argues that if the teaching of Littleford to provide a guide catheter having a centering balloon is applied to Gray, one would not have a filter coupled to the guidewire since Littleford also teaches that a guidewire may be withdrawn prior to the insertion of laser or angioplasty balloon catheter. Littleford is applied to Gray in order to teach a guide catheter. Incorporating this teaching into the apparatus and method of Gray does not require the incorporation of every element of the method disclosed in Littleford. Examiner notes that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references

would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant additionally argues that the balloon of Littleford is not capable of blocking the vasculature in which it is deployed, and points to the embodiment shown in Figure 9 of Littleford. As described in the brief description of Figure 9, this is an alternative embodiment in which the expandable balloon is configured to permit fluids to pass over the balloon. The primary embodiment of the balloon disclosed in Littleford is cylindrical as may be seen in Figure 3. Said balloon is capable of stopping fluid from flowing distally past the distal region of the shaft when the balloon is expanded.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Eric Blatt
571-272-9735

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